NOSOCOMIAL TRANSMISSION OF HEPATITIS B VIRUS INFECTION AMONG RESIDENTS WITH DIABETES IN A SKILLED NURSING FACILITY

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ABSTRACT

OBJECTIVE: To identify exposures associated with acute hepatitis B virus (HBV) infection among residents with diabetes in a skilled nursing facility.

DESIGN: Residents from Unit 3 and other skilled nursing facility residents with diabetes were tested for serologic evidence of HBV infection. Two retrospective cohort studies were conducted. Potential routes of HBV transmission were evaluated by statistical comparison of attack rates.

SETTING: A 269-bed skilled nursing facility.

PARTICIPANTS: All skilled nursing facility residents with diabetes and skilled nursing facility residents who lived on the same unit as the index case (Unit 3) for some time during the case's incubation period.

RESULTS: All 5 residents with acute HBV infection had diabetes and resided in Unit 3. The attack rate among the 12 patients with diabetes in Unit 3 was 42%, compared with 0% among 43 patients without diabetes (relative risk, 37.2; 95% confidence interval, 4.7 to ∞). Acutely infected patients with diabetes received more morning insulin doses ($P = .05$), and more insulin doses ($P = .03$) and finger sticks ($P = .02$) on Wednesdays than did noninfected patients with diabetes. Two chronically infected patients with diabetes in Unit 3 were positive for hepatitis B e antigen and regularly received daily insulin and finger sticks. Of the 4 acute and 3 chronically infected residents from whom HBV DNA was amplified, all were genotype F and had an identical 678-bp S region sequence. Although no component of the lancets or injection devices was shared among residents, opportunities for HBV contamination of diabetes care supplies were identified.

CONCLUSIONS: Contamination of diabetes care supplies resulted in resident-to-resident transmission of HBV. In any setting in which diabetes care is performed, staff need to be educated regarding appropriate infection control practices (*Infect Control Hosp Epidemiol* 2002;23:313-318).

Hepatitis B virus (HBV) is transmitted by percutaneous and permucosal exposures to infected blood or body fluids, either directly or indirectly through contact with contaminated environmental surfaces or hands of personnel. Nosocomial transmission of HBV has previously been associated with inadequately disinfected equipment and unsafe injection practices, including contamination of multidose, multipatient medication vials and fingerstick blood sampling devices with reusable components.[1-6] We describe the investigation of an outbreak of acute HBV infection among patients with diabetes in a skilled nursing facility that used single-use fingerstick blood sampling devices.

On November 30, 1999, a 74-year-old woman with diabetes who had hemodialysis-dependent chronic renal failure acquired acute hepatitis and died during hospitalization. Hepatitis B was confirmed by the presence of hepatitis B surface antigen (HBsAg) and IgM antibody to hepatitis B core antigen (IgM anti-HBc). The woman had resided in Unit 3 of a 269-bed skilled nursing facility since July 29, 1999. A review of routine HBV serologic test results among other patients who attended the hemodialysis center did not identify other patients with markers for acute or chronic HBV infection, suggesting that HBV transmission had occurred at the skilled nursing facility.

METHODS

Case Ascertainment

Clinical records of all residents of the skilled nursing facility were reviewed to identify residents with recent hos-

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pitalizations for liver disease, serologic markers of viral hepatitis, or abnormal serum aminotransferase levels (alanine aminotransferase or aspartate aminotransferase).

Blood samples for serologic testing were requested from all current residents of Unit 3 and other current skilled nursing facility residents who had resided in Unit 3 during the incubation period of the index case resident. Because diabetes care procedures have previously been implicated as a source of HBV transmission among residents of skilled nursing facilities, serologic testing was also performed on all other skilled nursing facility residents with diabetes.

Definitions

A case of acute HBV infection was defined as any skilled nursing facility resident who tested positive for IgM anti-HBc. Chronic HBV infection was defined as any skilled nursing facility resident who tested positive for HBsAg and total anti-HBc, but negative for IgM anti-HBc. Individuals testing positive for total anti-HBc (and negative for HBsAg) were considered immune to HBV infection. Susceptible individuals were defined as those residents who tested negative for total anti-HBc.

Cohort Studies

To identify exposures associated with acute HBV infection, a retrospective cohort study was conducted among HBV-susceptible skilled nursing facility residents (including those who had acute infection) who resided in Unit 3 between July 15 and December 15, 1999. To identify exposures associated with acute HBV infection among patients with diabetes, a second cohort study was conducted among HBV-susceptible residents with diabetes who resided in Unit 3 during the study period.

We obtained resident demographic and medical information by reviewing the facility's medical records and computerized database. Cognitive impairment among the skilled nursing facility residents precluded individual interviews. For the retrospective cohort study of patients with diabetes in Unit 3, we also examined dates of injected medications, phlebotomy, fingerstick glucose procedures, wound dressing changes, and podiatry, dental, and optometry visits. Exposures to fingerstick glucose monitoring, administration of insulin, and care by specific nursing staff were determined for each day during the study period. We also collected data about the time of day and day(s) of the week that fingerstick monitoring and insulin were administered. We interviewed and observed skilled nursing facility employees and reviewed facility records to determine general policies and procedures, infection control practices, and methods used for fingerstick glucose monitoring and administration of medications during the study period.

Laboratory Studies

Serum specimens were tested at the Hepatitis Reference Laboratory, Centers for Disease Control and Prevention (CDC), for anti-HBc (total and IgM) and HBsAg using standard assays (*CORZYME*, *CORZYME*-M, AUSZYME Mono, and HBsAg Quantitation Panel, Abbott Laboratories, Abbott Park, IL). Specimens from residents with acute or chronic infection were tested for hepatitis B e antigen (HBeAg) using a standard assay (DiaSorin HBe assay, DiaSorin, Inc., Stillwater, MN) at Quest Laboratories (Atlanta, GA).

To detect HBV DNA, the S region of the HBV genome was amplified using polymerase chain reaction.[7] Sequences of the entire 678-bp region encoding HBsAg were determined by direct sequencing using internal primers and dRhodamine terminators, and analyzed with a 377A DNA sequencer (Applied Biosystems, Inc., Foster City, CA). Sequences were aligned and compared with each other and with previously reported HBV sequences selected from GenBank using Pileup (Genetics Computer Group, Madison, WI).

Statistical Analysis

Attack rates and frequencies of exposure were compared by calculating relative risks with 95% confidence intervals (Fisher's exact test). Differences in proportions were compared using Fisher's exact test. Medians of continuous variables were compared using the Wilcoxon rank sum test. To control for length of residence in Unit 3, the median numbers of finger sticks or insulin doses per morning of residence in Unit 3 were compared. A P value of less than .05 was considered significant. Statistical calculations were conducted using Epi Info (version 6.04; CDC, Atlanta, GA) or SAS (version 7.0; SAS Institute, Cary, NC) software. For calculation of the relative risk when the denominator was 0, we used a modified Wolff estimate (addition of 0.5 to each cell in the 2×2 table).[8]

RESULTS

Cases

Of 117 eligible skilled nursing facility residents, 114 (97%) were tested for markers of HBV infection, including 79 (98%) of 81 residents of Unit 3 and 35 (97%) of 36 patients with diabetes who resided in the rest of the skilled nursing facility. Five (4%) had acute HBV infection; 3 residents were female, 4 were white, and 1 was Hispanic. The median age was 74 years. All 5 residents with acute infection had resided in Unit 3 for at least some time between July 15 and December 15, 1999, but all did not reside in Unit 3 at the same time. All had diabetes and received fingerstick glucose monitoring; 4, including the index case resident, received insulin during the study period. In addition to the index case resident, only 1 other case resident had clinical symptoms (a flu-like illness) during the study period; although elevation of serum aminotransferase levels was documented, serologic testing for hepatitis B was not obtained during her illness.

Retrospective Cohort Study Among Unit 3 Skilled Nursing Facility Residents (Cohort Study I)

In addition to the 5 residents with acute infection, 21 (27%) of the 79 residents of Unit 3 had serologic markers of HBV infection, including 4 with chronic infection and 17 with resolved infection. Three of the 4 residents with

TABLE 1
RISK OF ACUTE HEPATITIS B VIRUS INFECTION AMONG SUSCEPTIBLE UNIT 3 SKILLED NURSING FACILITY RESIDENTS BY SELECTED EXPOSURES, JULY 15 TO DECEMBER 15, 1999 (N = 55)

Exposure	Infected/ Exposed (%)	Infected/ Unexposed (%)	Relative Risk* (CI_{95})
Diabetes care	5/12 (41.7)	0/43 (0)	37.2 (4.7 to ∞)
Received finger stick	5/13 (38.5)	0/42 (0)	33.8 (4.2 to ∞)
Received insulin	4/6 (66.7)	1/49 (2.0)	32.7 (3.9 to 842.0)
Received intramuscular, subcutaneous, or intravenous medications, including insulin	5/45 (11.1)	0/10 (0)	2.6 (0.3 to ∞)
Received influenza vaccine	3/38 (7.9)	2/17 (11.8)	0.7 (0.1 to 3.7)
Received phlebotomy	5/48 (10.4)	0/7 (0)	1.8 (0.2 to ∞)
Hospitalized between July 15, 1999 and December 15, 1999	1/21 (4.8)	4/34 (11.8)	0.4 (0.0 to 3.7)
Received podiatry care	3/35 (8.6)	2/20 (10.0)	0.9 (0.1 to 9.7)

CI_{95} = 95% confidence interval.
*Calculated using the Wolff estimate of relative risk when the denominator is 0.[6]

TABLE 2
SKILLED NURSING FACILITY UNIT 3 RESIDENTS WITH DIABETES WITH ACUTE HEPATITIS B VIRUS INFECTION COMPARED WITH UNINFECTED RESIDENTS WITH DIABETES BY FREQUENCY OF SELECTED EXPOSURES, JULY 15 TO DECEMBER 15, 1999 (N = 12)

Exposures	Acutely Infected (n = 5) Median (Range)	Uninfected (n = 7) Median (Range)	P
Finger sticks	21 (14–612)	30 (0–218)	.74
Finger sticks/day	2.0 (0.14–4.0)	0.43 (0–1.91)	.25
Finger sticks in morning	21 (7–153)	12 (0–109)	.25
Finger sticks/morning	0.99 (0.14–1.0)	0.14 (0–0.96)	.14
Insulin doses	14 (0–307)	0 (0–31)	.10
Insulin doses/day	1.50 (0–2.0)	0 (0–1.03)	.07
Insulin doses in morning	7 (0–153)	0 (0–25)	.05
Insulin doses/morning	1.00 (0–1.0)	0 (0–0.83)	.05

chronic infection had diabetes, of whom 2 were positive for HBeAg. Both received insulin and fingerstick glucose monitoring; 1 received fingerstick glucose monitoring 4 times a day during the entire exposure period. Demographic characteristics (age, race or ethnicity, and gender) were similar regardless of infection status.

There were 50 residents in Unit 3 who were susceptible to HBV infection; the overall attack rate for residents of Unit 3 was 5 (9%) of 55. The attack rate for patients with diabetes in Unit 3 was 5 (42%) of 12, compared with 0 (0%) of 43 for the residents of Unit 3 who did not have diabetes (relative risk, 37.2; 95% confidence interval, 4.7 to ∞). The only percutaneous exposures associated with infection were those related to the medical care of patients with diabetes, and included receiving finger sticks and insulin (Table 1).

Retrospective Cohort Study Among Patients With Diabetes in Unit 3 (Cohort Study II)

All patients with diabetes in Unit 3 except 1 received fingerstick blood glucose monitoring. Patients with diabetes in Unit 3 who received insulin were more likely to acquire acute HBV infection compared with patients with diabetes who did not receive insulin, but the difference was not statistically significant (4 [67%] of 6 vs 1 [17%] of 6; $P = .12$). However, patients with diabetes who had acute HBV infection received significantly more morning insulin doses and more insulin doses per morning in Unit 3 compared with uninfected patients with diabetes (Table 2). In addition, patients with diabetes who had acute HBV infection received a higher median number of total insulin doses, insulin doses per day, finger sticks, and finger sticks per day compared with uninfected patients with diabetes, although none of these associations was statistically significant (Table 2).

Most finger sticks were performed on Wednesdays, and 4 residents of Unit 3, including 2 with acute HBV infection, received finger sticks only on Wednesday. Both the median number of insulin doses given on Wednesdays and the median number of insulin doses and finger sticks given per Wednesday were associated with acute HBV infection (Table 3).

TABLE 3
FREQUENCY OF SELECTED EXPOSURES ON WEDNESDAYS AMONG UNIT 3 RESIDENTS WITH DIABETES AND ACUTE HEPATITIS B VIRUS INFECTION COMPARED WITH UNINFECTED RESIDENTS WITH DIABETES, JULY 15 TO DECEMBER 15, 1999 (N = 12)

Exposures	Acutely Infected (n = 5) Median (Range)	Uninfected (n = 7) Median (Range)	P
Finger sticks	21 (2–84)	4 (0–30)	.07
Finger sticks/day	1.0 (1.0–4.0)	0.78 (0–1.0)	.02
Finger sticks in morning	21.0 (1–21)	0 (0–21)	.02
Finger sticks/morning	1.0 (1.0–1.0)	0 (0–1.0)	.01
Insulin doses	4 (0–42)	0 (0–4)	.04
Insulin doses/day	1.5 (0–2.0)	0 (0–0.8)	.03
Insulin doses in morning	4.0 (0–21)	0 (0–4)	.04
Insulin doses/morning	0.55 (0–1.0)	0 (0–0.8)	.05
Insulin doses at night (includes dinner and bedtime)	1 (0–21)	0 (0–4)	.03

To evaluate the possibility that HBV transmission had been ongoing prior to the exposure period of the index case resident, we compared the overall prevalence of HBV serologic markers among all patients with diabetes and patients with diabetes in Unit 3 with patients who did not have diabetes in Unit 3. The prevalence of HBV infection both among all residents with diabetes (23 [40%] of 57) and among residents of Unit 3 with diabetes (15 [68%] of 22) was significantly higher than that among residents of Unit 3 who did not have diabetes (11 [19%] of 57; $P < .05$). In addition, patients with diabetes in the skilled nursing facility who had evidence of HBV infection had a longer stay compared with susceptible patients with diabetes in the skilled nursing facility (561 vs 189 days; $P = .02$), as did patients with diabetes in Unit 3 with evidence of HBV infection compared with susceptible patients with diabetes in Unit 3 (median, 873 vs 249 days; $P = .10$).

Relatedness of HBV Isolates

Of 9 specimens from residents of Unit 3 with acute or chronic infection submitted for molecular testing, 7 (4 acute and 3 chronic) had sufficient HBV DNA for sequencing. All specimens were genotype F and had identical S region sequences. Heterogeneity observed between S region sequences from the skilled nursing facility specimens and previously published unrelated sequences ranged from 0.4% to 4.2% for other genotype F sequences and from 5% to 9.6% for sequences from other HBV genotypes.

Of the 7 skilled nursing facility residents with identical sequences, 6 (4 acute and 2 chronic) received blood glucose monitoring and 5 (3 acute and 2 chronic) also received insulin. The 2 chronically infected patients with diabetes who received both blood glucose monitoring and insulin were HBeAg positive.

Diabetes Care Practices

Two nurses licensed to administer medications usually staffed day and evening shifts, but the night shift usually had only one such nurse. Although 37% of finger sticks were performed in the morning, the night shift nurse administered all morning finger sticks and insulin doses. On Wednesday mornings, the morning workload increased from 6 to 8 residents to as many as 11.

Since May 1999, a hand-held glucose monitor had been used that determined blood glucose by a conduction technique that did not require the blood-contaminated end of the 1½-inch glucose test strip to contact the monitor directly. Before measuring blood glucose, the nurse would place a fresh test strip into the monitor. Nurses used single-use disposable fingerstick blood sampling devices to conduct glucose testing; no components intended for use with multiple residents were used. After the finger stick, the resident's lanced finger was placed onto the distal end of the test strip to transfer a drop of blood. Hemostasis was obtained using an alcohol wipe or gauze pad and pressure, and often was performed while the monitor was calculating the glucose measurement. Nurses deposited used sharps in containers found in the resident rooms and on the hallway medication cart. Nurses reported that fingerstick blood glucose monitoring was performed consecutively on residents by hallway or entire unit. Several residents of Unit 3 received finger sticks up to 4 times per day with no associated orders for insulin; these residents' blood sugar results were repeatedly within the normal range.

Multidose vials of insulin designated for individuals were stored in a medication refrigerator located near the Unit 3 nursing station and were often bundled together by a rubber band or placed in small plastic trays in groupings. Insulin vials were not shared among residents. Nurses used only disposable, self-sheathing needles intended for single use to administer insulin and other medications. Because residents with diabetes shared similar insulin dose schedules, nurses commonly transported insulin vials, syringes, and medication sheets between residents in the plastic caddy to administer insulin doses consecutively, sometimes administering insulin immediately following fingerstick blood glucose measurement.

DISCUSSION

The results of this investigation indicate that resident-to-resident transmission of HBV occurred in a skilled nursing facility. HBV transmission most likely occurred during the administration of insulin or fingerstick blood glucose monitoring. The association between infection and receipt of insulin was stronger than the association between infection and finger sticks. However, all 5 case residents received finger sticks, whereas 1 case resident did not have any documented insulin doses during the study period. Several factors made it difficult to determine whether insulin injections or finger sticks were the most likely mode of transmission. Both procedures occurred in 4 of the 5 case residents, and all susceptible patients with diabetes who received insulin also received finger sticks. Because of the long incubation period for HBV infection, it was not possible to accurately determine when cases became infected.

It was not possible to identify a specific individual as the source of the outbreak. Unit 3 housed several chronically infected residents with diabetes and all 5 case residents for some portion of their incubation periods. Because at least 1 chronically infected HBeAg-positive resident received a finger stick during each round of finger sticks, all patients with diabetes were potentially exposed to blood containing HBV whenever they received insulin or fingerstick glucose monitoring. Some HBV-infected residents may also have been infected by other acutely infected residents. Alternatively, the source for HBV infections might have been a skilled nursing facility healthcare worker. Skilled nursing facility healthcare workers were not tested for HBV infection, because infection was not associated with exposure to any specific healthcare worker. However, no skilled nursing facility healthcare worker reported a history of hepatitis or had been reported to the California Department of Health Services to have HBV infection in the past.

Several observations provide evidence that multiple episodes, rather than a single episode, of transmission had occurred in this skilled nursing facility, and that transmission may have been ongoing for a period longer than the 6 months identified in this outbreak. First, the 5 residents with acute infection did not reside in Unit 3 at the same time during the exposure period. Second, the overall prevalence of HBV infection was higher among residents with diabetes than among residents without diabetes, and the median length of stay at the skilled nursing facility was longer for infected residents with diabetes compared with uninfected residents with diabetes. Finally, in addition to at least 4 residents with acute HBV infection, 3 residents with chronic infection were infected with the same HBV genotype containing identical surface gene sequences. Limited studies of HBV-infected individuals in the United States have not reported finding genotype F, although the prevalence and heterogeneity of this genotype in the U.S. population is not well characterized.

This investigation suggests that transmission of HBV among patients with diabetes can occur despite the use of completely disposable single-use fingerstick devices and single-use medication vials. Previous investigations of nosocomial transmission of HBV have implicated spring-loaded fingerstick devices with reusable components or multidose, multipatient medication vials.[2-4,9] In 1997, the CDC recommended that these fingerstick devices be restricted for individual use and emphasized that components of these devices likely to be contaminated by blood should be discarded after each use.[10] In the outbreak reported here, contamination of gloves, glucose monitors, insulin vials, or other surfaces with blood from an HBV-infected resident may have allowed the introduction of HBV into the fresh fingerstick wound or subcutaneous injection site of another resident. Contaminated hands or gloves could transfer HBV to the glucose monitor, and hands or gloves could then transfer HBV to a new finger stick. Transmission via finger stick could also occur if a fingerstick blood sampling device previously used on an HBV-infected resident was reused on a susceptible resident. The fingerstick blood sampling devices did not have a mechanism to prevent reuse, although a contaminated lancet would be easily distinguished from an unused lancet by the absence of the plastic seal.

If transmission occurred via insulin injections, three possible mechanisms can be postulated, all of which involve breaks in standard infection control procedures. The first possibility is that one or more insulin vials intended for use in individual residents were contaminated with HBV, and the contents used for injection in more than one resident. The second possibility is that opened vials of insulin were contaminated by hands or contact with other contaminated surfaces, allowing insulin or an injection needle to become contaminated as it passed through a rubber stopper that had not been properly decontaminated with alcohol. Finally, breaches of infection control practices, such as inadvertent reuse of contaminated needles previously used on HBV-infected residents, are possible.

In our investigation, asymptomatic, viremic residents served as a source for transmission of HBV. Both acute and chronic HBV infections had gone unrecognized until the index case resident's illness prompted the serologic survey. These findings highlight the need to adhere to standard infection control practices when conducting diabetes care procedures in any healthcare setting. To prevent cross-contamination and contamination of environmental surfaces, staff should be reminded to avoid transportation of clean supplies from resident to resident when performing fingerstick blood sampling procedures, to prepare medications such as insulin in a clean area, to wear gloves during fingerstick blood sampling, and to change gloves between residents. Environmental surfaces such as the glucose monitor should be decontaminated regularly and, whenever contamination with blood or body fluids is suspected, with standard hospital disinfectants.[10,11] Schedules for fingerstick blood sampling, insulin administration, and blood glucose measurements should be regularly reviewed to reduce the number of percutaneous procedures to the minimum necessary for management of diabetes.

This investigation indicates that cross-contamination of medical supplies during routine diabetes care may be a source of HBV infection for hospitalized patients with diabetes. Furthermore, transmission may be difficult to recognize and can occur during an extended period of time. Prevention of HBV transmission among patients with diabetes should be achievable by adherence to standard infection control precautions. Periodic staff education and demonstration of proficiency can promote compliance with these recommendations.

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